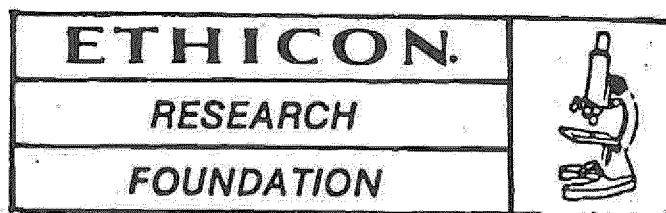


# **EXHIBIT LL**

84-1162

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BONERVILLE, NEW JERSEY 08876

To: Dr. R. L. Kronenthal

May 2, 1984

Subject: EXAMINATION OF PROLENE\* (POLYPROPYLENE)  
SUTURES FROM HUMAN CARDIOVASCULAR EXPLANTS

cc: Dr. A. W. Fetter  
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ERF ACCESSION NO.

84-194

PROJECT NO. 16104

SUMMARY

Six, formalin fixed tissue explants, containing PROLENE suture were received for evaluation of surface cracking and tensile strength measurement. Samples 1-5 were received from Dr. Margaret Bellingham, Stanford University Medical Center, and had PROLENE suture in residence from 1 year 2 months to 4 years 3 months post-op, size 3-0 and 4-0. Sample 6, size 5-0, was sent by Dr. Richard Sanders, Denver Colorado and had PROLENE in residence for 7 years.

Continuous PROLENE suture lines were carefully removed from the fixed cardiovascular specimens while keeping sutures wet. Subsequently, sutures were examined by light microscopy while wet and dry. Histological preparations of PROLENE cross-sections in tissue were stained in Phloxine and examined for cracking. Sample 1-5 showed no surface cracking in light microscopic examinations of both explanted suture or histological sections. Sample 6 displayed severe surface cracking of a 3 to 4.5 micron layer as measured in histological cross-sections.

The average breaking strength remaining for size 3-0 was 76.5% (range 47% - to 93%) and for size 4-0 was 98.25% (range 86% - 110%) when compared to similar size controls. Only one length of 5-0 PROLENE was available for tensile strength measurement indicating 76% strength remaining for the 7 year specimen.

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